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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,079	12/22/2005	Francisco Romero	14700-008US1 F/USP288234	9471
26161	7590	02/05/2008	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	
			MAIL DATE	DELIVERY MODE
			02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,079	Applicant(s) ROMERO ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008 and 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 14 and 17 is/are allowed.
- 6) ☒ Claim(s) 10, 11, 13 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20071207</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The Sequence Listing filed January 15, 2008 was not accompanied by a statement that the sequence listing include no new matter, as required by 37 CFR 1.821(g) and/or 1.825(a).

Applicants' statement that the content "does not go beyond the original disclosure" does not comply with the requirement set forth in the rule.

Applicant must provide a statement that the Sequence Listing filed January 15, 2008 includes no new matter as required by 37 CFR 1.821(g) and/or 1.825(a).

The Sequence Listing filed January 15, 2008 was approved by STIC for matters of form.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 10, 11, 13, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is apparent that the cell line ES7-008 is required to practice the claimed invention. Note that cell line ES7-008 is recited in claim 13, and is the only specifically disclosed cell line capable of producing the intended compounds. As a required element, cell line ES7-008 must be known and readily available to the public or obtainable by a repeatable method set forth in the

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specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of cell line ES7-008. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining cell line ES7-008, and cell line ES7-008 does not appear to be a readily available material. Deposit of cell line ES7-008 would satisfy the enablement requirements of 35 U.S.C. 112, first paragraph.

As set forth at page 12, first paragraph, of the specification, deposit has been made under the terms of the Budapest Treaty. An affidavit or declaration by Applicant or someone associated with the assignee who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

4. Claims 10, 11, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure of preparing Applicants' compounds from a microorganism strain of the *Thermoactinomyces* genus, as is recited in instant claim 10. Page 12, second paragraph, of the specification recites that ES7-008 is "phylogenetically close to *Thermoactinomyces* genus"; however, the implication from the word "close" is that ES7-008 is not actually a member of the *Thermoactinomyces* genus. Page 18, first full paragraph, of the specification recites that "Strain ES7-008 was grouped with the *Thermoactinomyces* group";

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however, the implication from "grouped with" again is that strain ES7-008 is not actually a member of the Thermoactinomyces genus. This implication is underscored by the following sentence of the specification, in which strain ES7-008 is acknowledged to have a "differentiating trait" with respect to Thermoactinomyces. Pages 22-25 of the specification, also cited by Applicants as support for the new claim language, do not mention the genus Thermoactinomyces.

5. Applicant's arguments filed December 7, 2007 and January 15, 2008 have been fully considered but they are not persuasive.

With respect to the rejection under 35 U.S.C. 112, first paragraph, and the deposit of cell line ES7-008, the deposit receipt and viability statement provided by Applicants are acknowledged. However, Applicants' response did not address the need for an affidavit or declaration by Applicant or someone associated with the assignee who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. See 37 CFR 1.808.

6. Claims 1-9, 14, and 17 are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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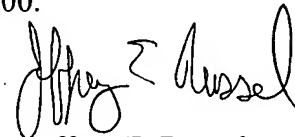
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.


Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

January 28, 2008